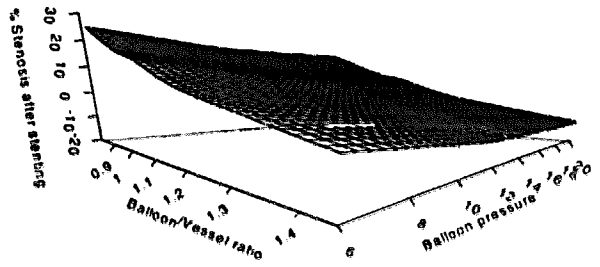

Conclusion: High balloon pressure may not be important as long as an adequate balloon to vessel ratio is maintained. This data indicates also that balloon to vessel ratio is crucial for adequate stent deployment.

1005-79 High Versus Normal Balloon Pressure Dilatation for Coronary Stent Placement. 6-Month Clinical and Angiographic Results From a Randomized Multicenter Trial

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Background: The impact of high balloon pressure for stent placement on clinical and angiographic outcome is still under discussion.

Methods: From May 96–May 97, 1126 patients were randomized to either "high pressure" implantation (575 interventions in 853 lesions; balloon pressure 16.7 ± 2.3 atm) or "normal pressure" implantation (572 interventions in 843 lesions; balloon pressure 11.1 ± 2.3 atm). Per protocol, only patients with cardiogenic shock or mechanical ventilation prior to the intervention, patients which already had been stented in the same vessel and patients without consent were excluded.

Results: Complete 4-week follow-up data are currently available in 98.4%. No significant differences in major adverse cardiac events (MACE) or the rate of stent thrombosis were seen between the two treatment groups (overall MACE rate 3.8%). As of today, 750 patients were eligible for 6-month follow-up (i.e. patients with successful stenting before January 31, 1997 and without MACE at 4 weeks) which has been completed in 85% of eligible patients.

Conclusions: These preliminary data suggest that early results are not significantly different. A complete clinical and angiographic 6-month follow-up will be available.

1005-80 Does Systematic High Pressure Deployment Improve Clinical Outcome After Palmaz-Schatz Coronary Stent Implantation?

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Previous reports emphasized the intravascular echography benefit of systematic high pressure (HP) stent deployment but its clinical benefit is still questionable. Since 01/94, we systematically used HP then, from 05/95 to 12/96, we decided to change our policy using an 8 to 12 atm. pressure and only more pressure in case of residual balloon indentation or stenosis ≥10%. We compared all consecutive Palmaz-Schatz stent implantations during these two time periods. Both groups received a ticlopidine/aspirin drug regimen. In HP group (N = 337 pts, 88% of stents with pressure ≥15 atm.) and regular pressure group (RP, N = 305 pts, 88% of stents with a pressure <15 atm.), clinical data were similar but a higher rate of acute MI PTCA in RP group. Angiographic data analysis revealed a higher rate of LAD PTCA and B2/C type lesion in RP pts. Procedural data and stent indication were similar in both groups, except pressure. In-hospital (InH) and 1 year follow-up (Fup) clinical results were (MACE = Death, Q MI, CABG):

	HP	RP	p
Clinical success (%)	97	98	NS
Stent thrombosis (%)	1.2	1.3	NS
InH MACE (%)	3	2	NS
Fup TLR (%)	13	10.6	NS
Fup MACE (%)	8	4.3	0.07
Event-free survival rate (%):	77.4	83.8	0.05

Thus, in our experience, a systematic use of HP Palmaz-Schatz stent deployment is not beneficial.

1005-81 Cost Impact of High Pressure Inflations and Therapy With Aspirin and Ticlopidine After Coronary Stenting

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Post-stent high pressure inflations (HPI) with aspirin and ticlopidine (AT) decrease subacute thrombosis and vascular complications (VC). To determine their influence on procedural and hospital costs, PTCA with stent placement for non-bailout indications (elective, suboptimal result post-balloon) in 663 patients (719 lesions) were reviewed: the initial 335 patients received coumadin (C) and no-HPI and the recent 328 patients received HPI and AT. Although the cost of devices currently used for non-bailout stent placement is slightly higher, total hospital costs have been reduced with HPI and AT, due to shorter hospital stay, less in-hospital CABG and less VC (table).

	No HPI + C	HPI + AT	P Value
Elective (%)	183 (55)	193 (59)	ns
Suboptimal Result (%)	152 (45)	135 (41)	ns
# Stents/Pt	1.2 ± 0.5	1.4 ± 0.7	<0.0001
IVUS (%)	28 (8.4)	67 (19.5)	<0.0001
In-Hospital CABG (%)	13 (3.9)	2 (0.6)	0.005
Vascular Complications	61 (18.3)	15 (4.6)	<0.0001
Death	6 (1.8)	2 (0.6)	0.29
Length of Stay (days)	6.5 ± 4.7	2.4 ± 5.1	<0.0001
Device Cost ($)	2729 ± 1003	3391 ± 1375	<0.0001
Total Hospital Cost ($)	12,488 ± 6404	8752 ± 3795	<0.0001

High pressure inflation with aspirin and ticlopidine have clearly improved patient care; outcome has improved dramatically while hospital costs have fallen.

1005-82 Assessment of Optimal Stent Implantation Using Computerized Pressure-Volume Curves

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Optimal stent deployment (D) is crucial to ensure short- and long-term patency and may require additional IVUS, an invasive and expensive tool. Pressure volume curves (PVC) of balloon inflation derived from our Computerized Automatic Pressure Sensor and Implantation Device (CAPSID), reflect resistance to stent opening. We calculated the area index between the PVC inside the stent (restrained inflation) and the PVC in air (unrestrained inflation). This area index that reflects the restrain imposed by the stent to balloon inflation, correlated with IVUS-MUSIC criteria for stent D: optimal D (group 1, 5 patients), borderline D (group 2, 6 patients) and poor D (group 3, 4 patients):

IVUS	Group 1	Group 2	Group 3
PVC area**	7.6 ± 4.5*	33.3 ± 12.1*	80.5 ± 48.3*

* $p < 0.05$ between all groups, ** normalized index × 1000

In 10 patients in whom angiography suggested need for higher pressure inflations, the area index decreased from 72.3 ± 3.4 to 26.9 ± 9.1. Ten patients who did not require additional inflation had an average area index of 19.9 ± 8.5 and a good outcome.

We Conclude: CAPSID PVC are a good guide for stent D and the need for further inflation, with good correlation to IVUS assessment.

1005-83 Transradial Approach for ad hoc Coronary Interventions: Procedural Results and Vascular Complications

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Background: Percutaneous transradial approach (PTRA) has the potential for low vascular complications, immediate post-procedural sheath removal and early ambulation. This series evaluate the safety and efficacy of this technique for the first 3053 consecutive procedures (proc.) during learning curves of 6 interventional cardiologists.

Results: Between July 94 and June 97, PTRA was attempted in 3053 proc in 2597 patients (pts), 73% male, with a functional radial arterial arch. In 260 pts, PTRA was performed up to 5 times, days to months later. Mean age was 60 years (17–94) with a wide range of weight (33–152 kg) and height (1.1–2.0 m). Coronary angiography was performed in 1560 pts (same-day discharge in 58%), *ad hoc* (78%) or elective angioplasty was performed in 1493 pts including coronary stenting in 670 pts. PTRA was not possible in 295 proc. (9.6%) Unsuccessful radial artery canulation (208), anatomical variation (49),